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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,472	12/19/2005	Signe M. Christensen	22460-003US1 / 1015US2	4416

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EXAMINER	
WOLLENBERGER, LOUIS V	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
09/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Notice to Comply with Sequence Rules

Applicant's reply filed 6/22//2009 to the Non-Final Action mailed 12/23/2008 is acknowledged. However, the reply is not fully responsive to the Action because Applicant has not provided as a separate part of the disclosure a sequence listing as required under 37 CFR §1.821(c).

MPEP 1893.03 states once the national stage application has been taken up by the examiner, prosecution proceeds in the same manner as for a domestic application with the exceptions that: (A) the international filing date (or, if appropriate, the priority date) is the date to keep in mind when searching the prior art; and (B) unity of invention proceeds as under 37 CFR 1.475. Thus, with regard to sequence compliance in the instant national stage application, the standards to be applied are the U.S. standards defined by 37 CFR 1.821-1.825. MPEP 2421.02 states these rules apply to all sequences in a given application, whether claimed or not.

In the instant case, requests for a sequence listing have been made in each of the two previous Actions, mailed 6/3/2008 and 12/23/2008. See in particular pages 2-3 of the Action mailed 12/23/2008 for the most recent requirement. In reply to the 6/3/2008 Action, filed 10/3/2008, Applicant stated a sequence listing would be submitted under separate cover. However, no sequence listing was provided by the time the next Action was prepared on or about 12/23/2008. In reply to the 12/23/2008 Action, filed 6/22/2009, Applicant submits no sequence listing is required in the instant application since the sequences disclosed in the application are not embraced by the definitions of nucleotide sequences given in the Rules. See Remarks filed 6/22/2009 at pages 7 and 8.

The Examiner respectfully disagrees.

> 37 CFR §1.821(a) states in part that Nucleotide and/or amino acid sequences as used in §§ **1.821** through **1.825** are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. "Specifically defined" means those amino acids other than "Xaa" and those nucleotide bases other than "n" defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25

The symbols and feature keys to be used in representing nucleotide sequences according to the WIPO Standard ST.25 (1998), Appendix 2, Tables 1 and 5, are provided in MPEP 2422. In the instant case, the sequences set forth at least at pages 27-29 and 32-42 of the instant application contain unbranched sequences of at least 10 "specifically defined" nucleotides and are, therefore, not excluded by 37 CFR §1.821(a). Each base in the sequence of each sequence shown can be represented by a symbol other than "n" from Table 1 of the WIPO Standard ST.25 (1998), Appendix 2, shown in MPEP 2422. Thus, Applicant may adequately define each nucleotide unit in the sequence of those shown in the specification using the appropriate lower case letter from Table 1 in conjunction with any or both of the feature keys "misc_feature" or "modified_base" from Table 5 to describe the structure and position of any and all non-standard nucleotides (including any of the LNAs shown at page 5 of the specification) that may be in the sequence when it cannot be described by any other feature key.

Examples from published and patented applications include:

```
<210> SEQ ID NO 8
<211> LENGTH: 18
<212> TYPE: DNA
<213> ORGANISM: Artificial
<220> FEATURE:
<223> OTHER INFORMATION: Oligonucleotide
<220> FEATURE:
<221> NAME/KEY: misc_feature
<222> LOCATION: (1)..(17)
<223> OTHER INFORMATION: Residues 1, 3, 5, 7, 9, 11, 13, 15 and 17 are
      2'-O-methyl-D-uridine

<400> SEQUENCE: 8

ututututut utututut                                              18
```

<210> SEQ ID NO 26
<211> LENGTH: 33
<212> TYPE: DNA
<213> ORGANISM: Artificial Sequence
<220> FEATURE:
<223> OTHER INFORMATION: oligonucleotide
<220> FEATURE:
<221> NAME/KEY: misc_feature
<222> LOCATION: (2)..(2)
<223> OTHER INFORMATION: 2'-4' cyclic linkage

<400> SEQUENCE: 26

gngntngttn ssssssssss ssssstgtcg ttg

<210> SEQ ID NO 45
<211> LENGTH: 12
<212> TYPE: DNA
<213> ORGANISM: Artificial Sequence
<220> FEATURE:
<223> OTHER INFORMATION: Description of Artificial Sequence: Synthetic oligonucleotide
<220> FEATURE:
<221> NAME/KEY: modified_base
<222> LOCATION: (1)..(1)
<223> OTHER INFORMATION: LNA monomer
<220> FEATURE:
<221> NAME/KEY: modified_base
<222> LOCATION: (3)..(5)
<223> OTHER INFORMATION: LNA monomer
<220> FEATURE:
<221> NAME/KEY: modified_base
<222> LOCATION: (7)..(9)
<223> OTHER INFORMATION: LNA monomer
<220> FEATURE:
<221> NAME/KEY: modified_base
<222> LOCATION: (11)..(12)
<223> OTHER INFORMATION: LNA monomer

<400> SEQUENCE: 45

ngganagntn cb 1

The miscellaneous feature generally describes the non-standard feature in as much detail as necessary to describe the complete structure of the nucleotide sequence.

37 CFR §1.821(c) states in part that "Patent applications which contain disclosures of nucleotide and/or amino acid sequences must contain, as a separate part of the disclosure, a paper or compact disc copy (*see* § 1.52(e)) disclosing the nucleotide and/or amino acid sequences and associated information using the symbols and format in accordance with the requirements of §§ 1.822 and 1.823. This paper or compact disc copy is referred to elsewhere in this subpart as the "Sequence Listing."

However, while this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because it does not contain as a separate part of the disclosure a sequence listing in compliance with 37 CFR 1.821(a)-(c).

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Primary Examiner, Art Unit 1635
August 29, 2009

Notice to Comply	Application No.	Applicant(s)	
	10535472	CHRISTENSEN ET AL.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the specification**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
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